

REMARKS

The Examiner is thanked for the due consideration given the application. The specification has been amended to insert headings.

Claims 1-14 are pending in the application. The claims have been amended to improve their language in what is believed to be a non-narrowing fashion.

No new matter is believed to be added to the application by this amendment.

Rejections Under 35 USC §103(a)

Claims 1 and 10 have been rejected under 35 USC §103(a) as being unpatentable over LEISNER et al. (U.S. Patent No. 6,626,878) in view of HOLTERMANN et al. (U.S. Patent No. 4,846,798). Claims 2, 5, 7, 8 and 11 have been rejected under 35 USC §103(a) as being unpatentable over LEISNER et al. in view of HOLTERMANN et al. and further in view of WAGENKNECHT (U.S. Patent No. 5,167,661). Claims 3 and 12 have been rejected under 35 USC §103(a) as being unpatentable over LEISNER et al., HOLTERMANN et al. and WAGENKNECHT as applied to claim 2, and further in view of FENTON (U.S. Patent No. 5,429,626). Claims 4 and 13 have been rejected under 35 USC §103(a) as being unpatentable over LEISNER et al., HOLTERMANN et al. and WAGENKNECHT as applied to claim 2, and further in view of LERMAN (U.S. Patent No. 4,338,937). Claims 6 and 14 have been rejected under 35 USC §103(a) as being unpatentable over LEISNER et al., HOLTERMANN et al. and

WAGENKNECHT as applied to claim 2, and further in view of JONES et al. (U.S. Patent No. 5,912,059). Claim 9 has been rejected under 35 USC §103(a) as being unpatentable over LEISNER et al. and HOLTERMANN et al. as applied to claim 1, and further in view of SINGER (U.S. Patent No. 3,383,121). These rejections are respectfully traversed.

The present invention pertains to an ostomy device connection that is illustrated, by way of example, in Figures 4a, 4b, 5a and 5b of the application, which are reproduced below.

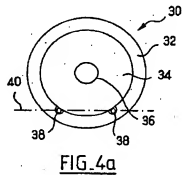


FIG. 4a

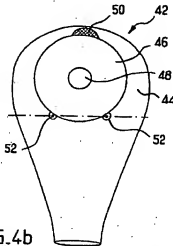


FIG. 4b

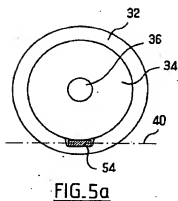


FIG. 5a

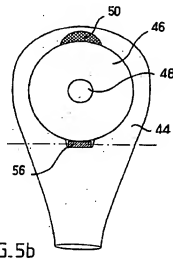
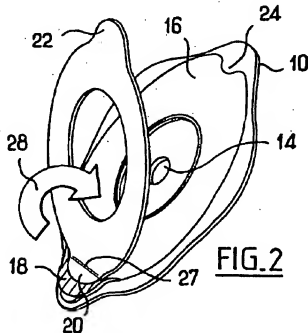
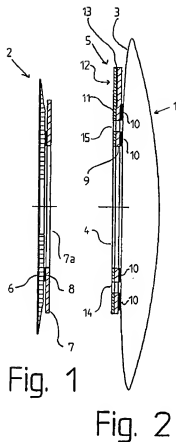


FIG. 5b

In the present invention, as typically set forth in claim 1, a pouch 42 is positioned relative to the fixing device 30 so that a hole 36 of the fixing device is in communication with a hole 48 of the collection pouch 42 and the fixing device 30. Two connecting portions 14,34,36 can cooperate with each other by means of adhesive-bonding in a plane which is practically perpendicular relative to the axes of the holes 14,34,46 of the pouch and the fixing device. See also Figure 2 of the application, reproduced below.



LEISNER et al. pertain to an ostomy device with a perforated flange. The Official Action refers to Figures 1 and 2 of LEISNER et al., which are reproduced below.



The Official Action acknowledges that LEISNER et al. fail to disclose an ostomy connection device such that the collection pouch and the fixing device comprise complementary fixing elements which are intended to limit the possibilities for relative displacement of the pouch and the fixing device so that the two connection portions have practically only one possible relative position when they are adjacent, this position corresponding to the alignment of the holes of the fixing device and the collection pouch (see claim 1 of the present invention).

The Official Action refers to Figures 2 and 3 of HOLTERMANN et al., reproduced below, to address the deficiencies of LEISNER et al.

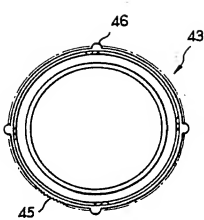


FIG. 2

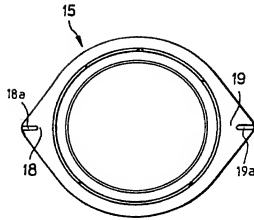


FIG. 3

The Official Action asserts that HOLTERMANN et al. teach the use of complementary fixing elements (46, 19a) for a collection pouch and a fixing device. However, the elements utilized in the Official Action (46, 19a) are not fixing elements analogous to the two connection portions according to the present invention, but are limiting elements for stopping the screwing of the end piece 43 having screw threads 48 on the end piece 15 having screw threads 22. The true complementary fixing elements are the screw threads 48, 22 which inter-engage during a rotation of a "quarter of a turn". So, there is no "only one possible relative position" when the two connection portions are adjacent because the threads 48, 22 have a range covering 90° for the relative displacement of the two connection portions.

If one assumes that the complementary fixing elements are the projections 46 and the thickened portions 19a, as suggested by the Official Action, and that these teachings are to

be combined to the teachings of LEISNER et al., the adhesive layer of LEISNER et al. (column 6, lines 20-30) would be coated on a surface of end piece 15 or 43, as soon as a portion of this surface (normal to the axis A-A of Figure 7) would touch the complementary surface of the other end piece 43 or 15 respectively.

Thus, the relative displacement by rotation would be prevented by the adherence of the two surfaces. On one hand, the two end pieces could not further rotate so that the projections 46 and the thickened portions 19a could not be in contact and, on the other hand, the sealing of the two surfaces would not be complete, so that odors could escape between the two surfaces.

Moreover, if the rotation could be completed, the cooperation of the projections 46 with the thickened portions 19a could not be provided before removing the protective sheet from the adhesive surface, as is set forth in claim 1 of the present invention.

The modification of the ostomy device connection of LEISNER et al. with the complementary fixing elements, as taught by HOLTERMANN et al., would thus not give a connection usable for ostomy pouches. A *prima facie* case of unpatentability has thus not been made over claim 1. Claims depending upon claim 1 are patentable for at least the above reasons.

Regarding claim 10, the Official Action at page 5 asserts that LEISNER et al. disclose:

[T]he connection characterized in that the portion having the adhesive surface is intended to be detached in one direction after use, and the configuration of this adhesive surface is such that the total length of the face for detaching by means of peeling, in a direction which is generally perpendicular relative to the detaching direction, is modulated so that it is substantially constant over the majority of the length of the portion having the adhesive surface in the detaching direction.

However, the two quoted portions of LEISNER et al. state on one hand that "the connecting elements comprise a substantially annular second flange, which is fixedly connected to the collecting bag via a substantially annular second connecting section and is designed for removable and adhesive connection with said first flange" (column 2, lines 32-33) and on the other hand that "the annular flange is designed for removable and adhesive connection with a second flange connected with a body side member of an ostomy appliance by a second connecting section." (column 3, lines 3-5).

Neither of the two quoted portions of LEISNER et al. teaches or infers that the total length of the face in a direction which is perpendicular relative to the detaching direction is modulated so that it is substantially constant over the majority of the length of the portion having the adhesive surface.

Regarding claim 2, the Official Action at page 6 acknowledges that LEISNER et al. and HOLTERMANN et al. fail to disclose a connection characterized in that "the complementary

fixing elements form an articulation device which delimits a pivot axis remote from the holes of the fixing device and the collection pouch, the protective sheet being practically entirely at only one side of the pivot axis" (page 6, lines 4-8).

As stated by the specification, for example, in reference to Figures 4a, 4b, 5a, 5b and 6a, the only relative movement between the two connection portions is around the pivot axis. If another degree of movement would be possible, the two connection portions would not have practically only one possible relative position when they are adjacent.

At page 6, lines 11-13 the Official Action asserts: "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ostomy device connection of Leisner/Holtermann with the articulation as taught by Wagenknecht."

WAGENKNECHT pertains to an articulation device which makes it possible to position an elongated piece, which is capable of being pivoted through 360° according to an arrow A, and a second piece, which is capable of swiveling about a shaft according to an arrow B, the pieces being made integral with a U-shaped support in relation to which they can be locked. So, WAGENKNECHT pertains to a device allowing movement according at least to two pivot axes, and does not infer a movement around only one pivot axis, as is set forth in claim 2 of the present invention.



Regarding claims 3 and 12, FENTON utilizes two elements, similar to push-buttons, which are diametrically opposed in respect to the holes of a collection pouch and of a fixing device. The axis connecting the elements crosses the holes, and cannot define a pivot axis remote from the holes as specified by claim 2 from which claims 3 and 12 depend.

Regarding claim 9, SINGER fails to disclose a protective sheet of an adhesive layer which includes two portions which are folded in the form of a folder whose folds are adjacent on the adhesive surface so that this adhesive surface is completely covered, and the flap which is not adhesively-bonded to the adhesive surface has a gripping lug which extends beyond the limits of the adhesive surface. Moreover, the specification of SINGER does not even include the word "fold."

Also, none of the additional references addresses the deficiencies of LEISNER et al. and HOLTERMANN et al. inducing one of ordinary skill in the art to produce claim 1 of the present invention. A *prima facie* case of unpatentability has thus not been made. Claims depending upon claim 1 are thus also instantly patentable.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

Conclusion

The Examiner is thanked for considering the Information Disclosure Statement filed March 14, 2006 and for making an initialed PTO-1449 Form of record in the application.

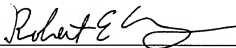
Prior art of record but not utilized is believed to be non-pertinent to the instant claims.

It is believed that the rejections have been overcome, obviated or rendered moot, and that no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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